

## **EXPLANATORY STATEMENT**

Issued by the authority of the Minister for Agriculture, Fisheries and Forestry

*Biosecurity Act 2015*

*Biosecurity Amendment (2022 Measures No. 1) Regulations 2022*

### **Legislative Authority**

The *Biosecurity Act 2015* (the Act) provides the regulatory framework for the management of diseases and pests that may cause harm to human, animal or plant health or the environment.

The Act gives effect to Australia's relevant international rights and obligations, including Australia's obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement provides for Australia's obligations with respect to the Appropriate Level of Protection (ALOP), which, for Australia, is a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to a very low level, but not to zero.

Section 645 of the Act provides that the Governor-General may make regulations prescribing matters that are required or permitted by the Act to be prescribed or that are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

### **Purpose**

The *Biosecurity Amendment (2022 Measures No. 1) Regulations 2022* (the Amendment Regulations) amend a number of provisions in the *Biosecurity Regulation 2016* (the Principal Regulation) relating to the conduct of risk assessments and update a superseded reference.

The Amendment Regulations seek to increase the transparency around the process by which risk assessments are conducted for the purposes of varying or revoking conditions of, or imposing further conditions on, a permit granted under the Act; or varying, suspending or revoking such a permit. The Amendment Regulations also align the risk assessment process with changes to the Act made by Schedule 5 to the *Biosecurity Amendment (Strengthening Biosecurity) Act 2022* (the Amending Act). Schedule 5 to the Amending Act is intended to increase transparency about the process by which risk assessments are conducted under the Biosecurity Act.

### **Background**

A risk assessment is conducted for particular goods or class of goods to ensure the biosecurity risk associated with the goods or class of goods is appropriately managed for the purposes of varying or revoking conditions of, or imposing further conditions on, a permit granted under the Act; or varying, suspending or revoking such a permit. Permits and conditions on permits play a central role in enabling the Australian Government to manage biosecurity risks.

The ALOP for Australia, which aims to reduce biosecurity risks to a very low level, but not to zero, is applied when conducting a risk assessment.

## **Impact and Effect**

The Amendment Regulations identifies the matters that the decision-maker must be satisfied of before making such a decision, as well as setting out the considerations that the decision-maker must or may consider before making such a decision. This provides greater certainty and clarity to stakeholders about the process by which risk assessments are conducted, thereby enhancing good public administration.

The Amendment Regulations do not alter the requirement that ALOP be applied in conducting a risk assessment, consistent with Australia's international obligations under the SPS Agreement. Similarly, the amendments do not change the role of the Director of Biosecurity as the decision-maker.

## **Consultation**

The Department of Health and Aged Care, the Department of Foreign Affairs and Trade and the Attorney-General's Department were consulted on the development of the Amendment Regulations.

The Office of Best Practice Regulation advised that a Regulation Impact Statement is not required (OBPR ID 44079).

The Department of Prime Minister and Cabinet and the Australian Public Service Commission were also consulted during the development of the risk assessment provisions made by Schedule 5 to the Amending Act.

Public consultation was not considered appropriate as the Amendment Regulations relate to an internal process within the Department of Agriculture, Fisheries and Forestry. The Amendment Regulations provide greater clarity and transparency of this process to stakeholders.

## **Details and Operation**

The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Amendment Regulations commence on the later of the day after registration on the Federal Register of Legislation and the day on which Schedule 5 to the Amending Act commences.

Details of the Amendment Regulations are set out in the [Attachment A](#).

## **Other**

The Amendment Regulations are compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in [Attachment B](#).

**Details of the *Biosecurity Amendment (2022 Measures No. 1) Regulations 2022***

**Section 1 – Name**

This section provides that the name of the instrument is the *Biosecurity Amendment (2022 Measures No. 1) Regulations 2022* (the Amendment Regulations).

**Section 2 – Commencement**

This section provides that the Amendment Regulations commence on the later of the day after the Amendment Regulations is registered on the Federal Register of Legislation and the day on which Schedule 5 to the *Biosecurity Amendment (Strengthening Biosecurity) Act 2022* (the Amending Act) commences. Schedule 5 to the Amending Act commences on the day after the Amending Act receives the Royal Assent.

**Section 3 – Authority**

This section provides that the Amendment Regulations are made under the *Biosecurity Act 2015* (the Act).

**Section 4 – Schedules**

This section provides that each instrument that is specified in a Schedule to the Amendment Regulations is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Amendment Regulations has effect according to its terms.

**Schedule 1 – Amendments**

***Biosecurity Regulation 2016***

**Item [1] – Section 5 (definition of *health certificate*)**

Item 1 updates the definition of ***health certificate*** in section 5 of the *Biosecurity Regulation 2016* (the Principal Regulation). This item replaces a reference to the *Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016* (the 2016 Determination) with the *Biosecurity (Conditionally Non-prohibited Goods) Determination 2021* (the 2021 Determination). The 2021 Determination repealed and replaced the 2016 Determination. This item ensures that the correct instrument is referred to in the definition of ***health certificate***.

**Item [2] – After subsection 44(1)**

Section 177 of the Act allows a person to apply to the Director of Biosecurity for a permit authorising the person, or a person acting on behalf of the person, to bring or import particular goods into Australian territory. Subsection 179(1) of the Act allows the Director of Biosecurity to grant a permit where a person has made an application under section 177. A permit may be granted subject to conditions as specified in the permit (see subsection 180(1) of the Act).

Subsection 180(2) of the Act allows the Director of Biosecurity to, in accordance with the regulations, vary or revoke a condition of a permit, or impose further conditions on such a permit. Section 44 of the Principal Regulation sets out the requirements that the Director of

Biosecurity must follow when seeking to vary or revoke conditions of, or impose further conditions on, a permit under subsection 180(2) of the Act.

Item 2 amends section 44 of the Principal Regulation by inserting a new subsection 44(1A) after existing subsection 44(1). New subsection 44(1A) requires that, before the Director of Biosecurity varies or revokes a condition of a permit, or imposes a further condition on a permit, granted under section 179 of the Act:

- a risk assessment must be conducted by a biosecurity worker in relation to the goods to which the permit relates; and
- the Director of Biosecurity must be satisfied that the Appropriate Level of Protection (ALOP) for Australia was applied in the conduct of the risk assessment.

The meaning of *biosecurity worker* is defined in the Act in section 14A, as inserted by item 3 of Schedule 5 to the Amending Act. The note following new subsection 44(1A) of the Principal Regulation clarifies for readers that **ALOP** is short for Appropriate Level of Protection and has the meaning given by section 5 of the Act.

The intention of this item is to clarify the process by which risk assessments are conducted for the purposes of the Director of Biosecurity varying or revoking conditions of, or imposing further conditions on, a permit relating to particular goods. This increases transparency about the process, by clearly identifying the matters that the Director of Biosecurity must be satisfied of before varying or revoking, or imposing further, conditions.

#### **Item [3] – Before paragraph 44(2)(a)**

Subsection 44(2) of the Principal Regulation outlines the matters the Director of Biosecurity must consider in deciding whether to vary or revoke a condition of a permit granted under section 179 of the Act.

Item 3 amends subsection 44(2) of the Principal Regulation by inserting new paragraph 44(2)(aa) before existing paragraph 44(2)(a). New paragraph 44(2)(aa) provides that the risk assessment that was conducted in relation to the goods to which the permit relates, is a matter that the Director of Biosecurity must consider in deciding whether to vary or revoke a condition of the permit.

The intention of this item is to clarify the process by which risk assessments are conducted for the purposes of the Director of Biosecurity varying or revoking conditions on a permit relating to particular goods. This increases transparency about the process, by clearly identifying the matters that the Director of Biosecurity must consider before varying or revoking conditions.

#### **Item [4] – Before paragraph 44(3)(a)**

Subsection 44(3) of the Principal Regulation outlines the matters the Director of Biosecurity must consider in deciding whether to impose a further condition on a permit granted under section 179 of the Act.

Item 4 amends subsection 44(3) of the Principal Regulation by inserting new paragraph 44(3)(aa) before existing paragraph 44(3)(a). New paragraph 44(3)(aa) provides that the risk assessment that was conducted in relation to the goods to which the permit relates, is a matter

that the Director of Biosecurity must consider in deciding whether to impose a further condition on the permit.

The intention of this item is to clarify the process by which risk assessments are conducted for the purposes of the Director of Biosecurity imposing further conditions on a permit relating to particular goods. This increases transparency about the process, by clearly identifying the matters that the Director of Biosecurity must consider before imposing further conditions.

#### **Item [5] – Subsection 44(4)**

Item 5 repeals existing subsection 44(4) of the Principal Regulation. This subsection is duplicative and no longer necessary due to the amendments being made by items 2, 3 and 4.

#### **Item [6] – After subsection 45(1)**

As noted above, section 177 of the Act allows a person to apply to the Director of Biosecurity for a permit authorising the person, or a person acting on behalf of the person, to bring or import particular goods into Australian territory. Subsection 179(1) of the Act allows the Director of Biosecurity to grant a permit where a person has made an application under section 177 and may, in accordance with the regulations, vary, suspend for a specified period, or revoke the permit (see subsection 181(1) of the Act).

Section 45 of the Principal Regulation sets out the requirements that the Director of Biosecurity must follow when seeking to vary, suspend or revoke a permit under subsection 181(1) of the Act.

Item 6 amends section 45 of the Principal Regulation by inserting a new subsection 45(1A) after existing subsection 45(1). New subsection 45(1A) requires that, before the Director of Biosecurity varies, suspends or revokes a permit granted under section 179 of the Act:

- a risk assessment must be conducted by a biosecurity worker in relation to the goods to which the permit relates; and
- the Director of Biosecurity must be satisfied that the Appropriate Level of Protection (ALOP) for Australia was applied in the conduct of the risk assessment.

The meaning of *biosecurity worker* is defined in the Act in section 14A, as inserted by item 3 of Schedule 5 to the Amending Act. The note following new subsection 45(1A) of the Principal Regulation clarifies for readers that **ALOP** is short for Appropriate Level of Protection and has the meaning given by section 5 of the Act.

The intention of this item is to clarify the process by which risk assessments are conducted for the purposes of the Director of Biosecurity varying, suspending or revoking a permit relating to particular goods. This increases transparency about the process, by clearly identifying the matters that the Director of Biosecurity must be satisfied of before varying, suspending or revoking a permit.

#### **Item [7] – Before paragraph 45(2)(a)**

Subsection 45(2) of the Principal Regulation outlines the matters the Director of Biosecurity must consider in deciding whether to vary, suspend or revoke a permit granted under section 179 of the Act.

Item 7 amends subsection 45(2) of the Principal Regulation by inserting new paragraph 45(2)(aa) before existing paragraph 45(2)(a). New paragraph 45(2)(aa) provides that the risk assessment that was conducted in relation to the goods to which the permit relates, is a matter that the Director of Biosecurity must consider in deciding whether to vary, suspend or revoke the permit.

The intention of this item is to clarify the process by which risk assessments are conducted for the purposes of the Director of Biosecurity varying, suspending or revoking a permit relating to particular goods. This increases transparency about the process, by clearly identifying the matters that the Director of Biosecurity must consider before varying, suspending or revoking a permit.

#### **Item [8] – Subsection 45(3)**

Item 8 repeals existing subsection 45(3) of the Principal Regulation. This subsection is duplicative and no longer necessary due to the amendments being made by items 6 and 7.

#### **Item [9] – In the appropriate position in Chapter 10**

Chapter 10 of the Principal Regulation provides for transitional matters. Item 9 provides for the transitional matters relating to the amendments in the Amendment Regulations by inserting a new section 123 in Chapter 10 of the Principal Regulation.

New subsection 123(1) provides that the amendments of section 44 made by the Amendment Regulations apply in relation to the variation or revocation of a condition of a permit, or the imposition of a further condition on a permit, on or after the commencement of new section 123, whether the permit was granted before, on or after that commencement.

New subsection 123(2) provides that the amendments of section 45 made by the Amendment Regulations apply in relation to the variation, suspension or revocation of a permit on or after the commencement of new section 123, whether the permit was granted before, on or after that commencement.

This item makes clear that the Amendment Regulations have prospective effect and apply in relation to the variation, suspension or revocation of a permit on or after commencement.

**Statement of Compatibility with Human Rights**

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

*Biosecurity Amendment (2022 Measures No. 1) Regulations 2022*

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the Legislative Instrument**

The *Biosecurity Amendment (2022 Measures No. 1) Regulations 2022* (the Amendment Regulations) amend a number of provisions in the *Biosecurity Regulation 2016* relating to the conduct of risk assessments and update a superseded reference.

The Amendment Regulations seek to increase transparency around the process by which risk assessments are conducted for the purposes of varying or revoking conditions of, or imposing further conditions on, a permit granted under the *Biosecurity Act 2015* (the Act); or varying, suspending or revoking such a permit. The Amendment Regulations also align the risk assessment process with changes to the Act made by the *Biosecurity Amendment (Strengthening Biosecurity) Act 2022*.

The amendments identify the matters that the decision-makers must be satisfied of before making such a decision, as well as setting out the considerations that the decision-makers must consider before making such a decision. This provides greater certainty and clarity to stakeholders about the process by which risk assessments are conducted, thereby enhancing good public administration.

The amendments enhance the transparency of requirements in relation to risk assessments but do not create or change any conditions or classes of goods. Therefore, the Amendment Regulations do not engage any of the applicable rights or freedoms.

**Human rights implications**

This Legislative Instrument does not engage any of the applicable rights or freedoms.

**Conclusion**

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

**Senator The Hon. Murray Watt**  
**Minister for Agriculture, Fisheries and Forestry**